State of California—Health and Human Services Agency
California Department of Public Health

MARK B HORTON, MD, MSPH
Director

ARNOLD SCHWARZENEGGER
Governor

Information Notice

November 8, 2010

To: Radioactive Materials Licensees

Subject: Adoption of Title 10, Code of Federal Regulations, Part 35 (10 CFR 35)

To maintain compatibility with the US Nuclear Regulatory Commission (NRC) and other Agreement States that have adopted 10 CFR 35, the California Department of Public Health (CDPH) has adopted relevant sections of 10 CFR 35, as published January 1, 2008. The adoption of these regulations has been approved by the Office of Administrative Law, with an effective date of January 1, 2011. A copy of 10 CFR 35 (January 1, 2008), is available at: http://www.access.gpo.gov/nara/cfr/waisidx_08/10cfr35_08.html.

This information notice is the fourth in a series of information notices designed to inform licensees of changes which will occur as a result of the adoption of 10 CFR 35, and also how the Radiologic Health Branch (RHB) expects licensees to respond to the changes. Information notices such as this will be posted on the RHB's Radioactive Materials Licensing webpage at: http://www.cdph.ca.gov/certlic/radquip/Pages/RadioactiveMaterials.aspx

The following information is provided to specifically call out regulatory changes and clarifications regarding the new regulations that licensees may find applicable to their operations and radiation safety programs.

After January 1, 2011, physicians currently authorized for Group 6 will be listed on the radioactive materials license with authorization for manual brachytherapy as authorized under 10 CFR 35.400. In order to grandfather a Group 6 physician who is currently using a High Dose Rate Remote Afterloader unit or Yttrium-90 TheraSpheres and/or SIRSpheres, a Best Vascular, Inc. Beta-Cath Intravascular Brachytherapy System, a NeoVista, Inc. Epi-Rad Ophthalmic System, or other devices as authorized under 10 CFR 35.1000, the licensee must submit a request to specifically add the physician to the license for 10 CFR 35.600 and/or 10 CFR 35.1000, and specify the device for authorization. Please submit Attachment 1 to add a physician for authorizations under 10 CFR 35.600 and/or 35.1000. After

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January 1, 2011, Attachment 1 cannot be used to submit an amendment request to add a physician for authorizations under 10 CFR 35.600 and/or 35.1000. If a physician authorized user is authorized only for one of the above modalities, or is specifically listed for that use, then no amendment is required.

- Licensees may make the following minor radiation safety program changes without submitting an amendment request:

    - Changes in the membership of the Radiation Safety Committee not involving the RSO or the Chairperson, as long as the selected individual will be providing similar representation as had the individual who is being replaced.

    - Replacement of a diagnostic imaging camera if it will be installed in the same room as the previous camera and does not require a change in radioactive transmission sources.

    - Replacement of radiation detection equipment if there is no change in the instrument type and function.

    - Addition of the use of a full service mobile provider, as long as the provider does not use the licensee's facility, equipment or personnel.

    - Changing the frequency of dosimetry exchange and evaluation as long as the maximum period is quarterly.

    - Changing dosimetry providers as long as the new provider is NVLAP accredited.

    - Change in the vendor who performs instrument calibrations as long as the vendor is licensed by the NRC, an Agreement State, or another Licensing State to perform the service.

    - Change in the vendor who performs sealed source leak tests as long as the vendor is licensed by the NRC, an Agreement State, or another Licensing State to perform the service.

- For clarification purposes, broad scope licensees may adopt the changes in these information notices, without RHB approval, as long as they are approved by the licensee's Radiation Safety Committee.

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- In addition, Sections 30321 and 30321.1 of Title 17, California Code of Regulations will be repealed. These sections include, in part, the requirement that a hospital or clinic have a custodian of sealed sources. Since a custodian of sealed sources is no longer required by regulation, it will not be necessary to list a custodian of sealed sources on the license. However, since the RSO is responsible for the radiation safety program, the responsibility for sealed sources will reside with the RSO or the RSO's designee.

To help licensees transition to the new requirements, RHB will hold two free half-day informational workshops that are open to members of the general public. The Southern California workshop is scheduled for December 6, 2010, at the Irvine Marriott Hotel, 18000 Von Karman Avenue, Irvine, California at 9:00 am. The Northern California workshop is scheduled for December 9, 2010, at the California Department of Public Health building, 1500 Capitol Avenue, Sacramento, California at 9:00 am. If needed, RHB will consider holding a second workshop at 1:00 pm, at the Irvine location.

Questions, comments and workshop reservations may be submitted to me, preferably by email at Ira.Schneider@cdph.ca.gov or by telephone at (916) 440-7976.

Sincerely,

Original Signed By: Ira Schneider

Ira Schneider
Senior Health Physicist
Radiologic Health Branch

Attachment 1

Request for 10 CFR 35.600 and/or 10 CFR 35.1000 Authorization

Please add *Dr._____

to Radioactive Materials License Number_____for 10 CFR 35.600 and/or 10 CFR 35.1000 authorization. I attest that the physician has performed procedures under this radioactive materials license using the following devices:

- ☐ High Dose Rate Remote Afterloader (HDR) unit.
- ☐ Low Dose Rate, Medium Dose Rate or Pulsed Dose Remote Afterloader unit.
- ☐ Best Vascular, Inc. Beta-Cath Intravascular Brachytherapy System.
- ☐ NeoVista, Inc. Epi-Rad Ophthalmic System.
- ☐ Isotrex GliaSite Radiation Therapy System.
- ☐ Yttrium-90 TheraSpheres or SIRSpheres.
- ☐ Other medical use of radioactive material or radiation from radioactive material as authorized by 10 CFR 35.1000.
  - Specify Radionuclide_____
  - Specify Device_____

_____	_____	_____
RSO Print Name	RSO Signature	Date
_____	_____	_____
Physician Print Name	Physician Signature	Date

***After January 1, 2011 this form may no longer be used.**
*Complete for each Physician and return the form only (no other paperwork is necessary) to the RHB at:

California Department of Public Health
Radiologic Health Branch, MS 7610
P.O. Box 997414
Sacramento, CA 95899-7414